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## Summary

| Document | Pages | Printed | Missed |
|---|---|---|---|
| WO009108215 | 25 | 25 | 0 |
| Total (1) | 25 | 25 | 0 |

FULL TEXT OF CASES (USPQ FIRST SERIES)
Ex parte REED AND GUNSALUS, 135 USPQ 34 (BdPatApp&Int 1962)

# Ex parte REED AND GUNSALUS

## (BdPatApp&Int)
## 135 USPQ 34

**Patent issued Aug. 14, 1962**
**Opinion dated June 27, 1961**
**U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences**

**Headnotes**

**PATENTS**

**1. Patentability -- Anticipation -- Patents--On copending applications (§ 51.2219)**

It is of no consequence that cited patents may have been filed and issued subsequent to applicants' filing date, since patents are used to establish as a matter of fact that compound is present in a material and is thus a product of nature and, hence, that under these circumstances no patent should issue on such product.

**2. Patentability--Subject matter for patent monopoly--Product of nature (§ 51.615)**

**Patentability--Subject matter for patent monopoly--Pure article (§ 51.617)**

Patent should not issue where claimed product occurred naturally in liver and other products, is merely extracted therefrom, and its growth stimulating properties are, and have been, recognized in the parent material; substance merely extracted from its parent material even in purer form is devoid of invention; however, substance may be patentable if it possesses a utility not possessed by parent material and not evident from the art.

**3. Patentability--Composition of matter (§ 51.30)**

**Specification -- Sufficiency of disclosure (§ 62.7)**

Claims are not rejected as being so unduly broad in esters as to fail to define invention, although examiner states that "lower alkyl esters" is inclusive of branched-chain alkyl compounds for which there is no support in specification; Board cannot agree that enormous number of compounds which do not necessarily have same utility is covered by claims, since homologues and isomers are presumed to have same utility differing normally as a matter of degree; since applicants disclose at least three lower alkyl groups and disclose that the lower alkyl esters are preferred, claims are adequately supported.

**4. Patentability--Composition of matter (§ 51.30)**

**Specification -- Sufficiency of disclosure (§ 62.7)**

Claim is rejected as unduly broad in salts since it includes toxic as well as nontoxic materials and is not supported by specification; another claim is rejected as unpatentable over the acid since there is no invention in preparing simple salts of any acid, as this is a well known chemical principle; salts would be readily apparent and thus obvious to one skilled in the art, particularly as there is nothing patentable in broad idea of forming the salts; furthermore, applicants specifically disclose only the simple salts as giving desired result; this affords insufficient basis for assuming that all metals of periodic system will be suitable for same intended purpose.

**Particular patents--Lipoic Acid**

3,049,549, Reed and Gunsalus, Lipoic Acid and Derivatives, claims 15 and 16 of application allowed; claims 12, 13, and 17 refused.

**Case History and Disposition:**



Appeal from Division 6.

Application for patent of Lester J. Reed and Irwin C. Gunsalus, Serial No. 417,918, filed Mar. 22, 1954. From decision rejecting claims 12, 13, and 15 to 17, applicants appeal (Appeal No. 300-46). Affirmed as to claims 12, 13, and 17; reversed as to claims 15 and 16.

On reconsideration, 135 USPQ 105 .

**Attorneys:**
HAROLD T. STOWELL and HAROLD L. STOWELL, both of Washington, D.C., for applicants.

**Judge:**
Before ASP and MAGIL, Examiners in Chief, and WILES, Acting Examiner in Chief.

**Opinion Text**

**Opinion By:**
WILES, Acting Examiner in Chief.

This is an appeal from the final rejection of claims 12 through 18. Claims 14 and 18 were allowed after the appeal and the appeal as to these claims will be dismissed.

Claims 12 and 17 are sufficiently representative and read as follows:

12. Compounds of the group consisting of a-lipoic acid; b-lipoic acid, the esters and the salts thereof.

17. The water-soluble non-toxic salts of a-lipoic acid.

The references relied on are:

Starker et al. 2,759,005 Aug. 14, 1956

Holly et al. 2,766,257 Oct. 9, 1956

Hornberger I 2,801,261 July 30, 1957

Publications referred to by appellants:

Stokstad et al., "Methods of Biochemical Analysis" by David Glick Volume 3, 1956, (Interscience Publishers) pages 29 and 30.

Reed et al., Journal of Biological Chemistry, Volume 192 (1951), pages 851-858 inclusive.

The alleged invention is directed to alpha-lipoic acid, its esters and salts. This acid is present in liver and appellants remove it therefrom by the extraction method set forth on pages 1 and 2 of the brief. The extraction method is not claimed in the present application.

The references are described on pages 1 and 2 of the examiner's answer. These patents have been referred to by the examiner only to show that alpha-lipoic acid widely occurs in nature and is a vitamin like or growth stimulating substance which has been extracted or isolated from liver although with difficulty.

[1] The examiner has rejected claims 12 and 13 as drawn to naturally occurring compounds and as support for this position the examiner refers to the above cited patents. While these patents may have been filed and issued subsequent to appellants' filing date, this is not deemed of consequence where as here they are used to establish as a matter of fact that a compound is present in a material and is thus a product of nature, hence, under these circumstances no patent should issue on such product (Ex parte Snell, 86 USPQ 496.

Even though the above cited patents make it quite plain that alpha-lipoic acid occurs naturally in liver and from which it has been isolated with difficulty, appellants have cited the above publications in support of their contention that "the scientific literature shows conclusively that a-lipoic acid is not present as such or in a microbiologically available form." However, they admit that it "must exist in such natural substances as liver and yeast mycelia but in that form it is of no value either to microorganisms or man." Based upon the latter arguments, appellants have cited and rely upon Sterling Drug, Inc. v. Watson, 135 F.Supp. 173, 108 USPQ 37 , and Merck and Company, Inc. v. Olin Mathieson Chemical Corporation, 253 F.2d 156, 116 USPQ 484 , as being authoritatively persuasive of the question of patentability herein.

In the Sterling case not only did the 1-arterenol exist in the human body in combination with other compounds but, as admitted by appellants, it was held it had "no therapeutic value unless isolated and available in its pure form."

According to appellants the court in the Merck case was of the opinion that " 'the natural fermentates are quite useless, while the patented compositions are of great medicinal and commercial value,' " and this seems to be the basis on which the validity of the patent was sustained.

These cases each differ from the present case in at least two respects. Here there is ample evidence that the claimed compound is present in liver and that liver has been used effectively for growth promotion or stimulation, whereas it appears from the cited cases that the parent material was not useful for the same purpose as the segregated material and it thus does not appear that the material could have been recognized as valuable for the stated purpose. In the Merck case the court was confronted also with the problem of sustaining the validity of an issued patent. These decisions therefore are considered inapposite to the present facts.

[2] In the present case there obviously is no question of sustaining the validity of an issued patent as we are concerned solely with the question of whether a patent should issue where the claimed product is shown to occur naturally in liver and other products, is merely extracted therefrom, and its growth stimulating properties are, and have been, recognized in the parent material.

We have had numerous occasions to consider the question of whether a substance merely extracted from its parent material even in purer form is devoid of invention, and we are of the view that In re Ridgway et al., 22 CCPA 1169, 76 F.2d 602, 25 USPQ 202 ; In re Marden et al., 18 CCPA 1057, 1931 C.D. 352, 409 O.G. 845, 47 F.2d 958, 8 USPQ 347 ; In re Merz, 25 CCPA 1314, 1938 C.D. 728, 497 O. G. 547, 97 F.2d 599, 38 USPQ 143 ; In re Macallum et al., 26 CCPA 1026, 1939 C.D. 415, 503 O. G. 309, 102 F.2d 614, 41 USPQ 146 , and In re King, 27 CCPA 754, 1940 C. D. 92, 510 O. G. 961, 107 F.2d 618, 43 USPQ 400 , constitute authority for holding that such products are not patentable. Other related authorities include In re Michalek, 34 CCPA 976, 1947 C. D. 310, 602 O. G. 669, 161 F.2d 253, 73 USPQ 385 , and In re Davis, 35 CCPA 767 1948 C. D. 123, 607 O. G. 370, 164 F.2d 626, 76 USPQ 109 . The principle established by the above cited decisions has been considered as controlling in sustaining the non-patentability of naturally occurring products in the following cases: Ex parte Windhaus, 15 USPQ 45 , in which claims directed to a product having the characteristics of vitamin D were held



unpatentable in spite of the fact that appellants apparently were the first to segregate it from the parent material; Ex parte Eldred, Patent File 1,978,079, in which the claim was directed to a hormone preparation segregated from the sex gland in which it occurred; Ex parte Stoll et al., Patent File 2,294,811, in which the claim held unpatentable was directed to a crystallized glucoside which had been extracted from red squill and was held to be a naturally occurring material in spite of the fact that it was present in the parent material in combination with tannin. (Being in combination in the parent material was considered immaterial in view of the holding in General Electric Company v. DeForest Radio Company, 28 F.2d 641, that tungsten was a natural product even though it did not occur as such in nature but only in combination with oxygen as $WO_3$.) ; Ex parte Cavallito, 89 USPQ 449 , in which the claimed allyl disulfide oxide antibiotic compound had been separated from ground garlic in which it occurred. (Isolation of the active component and determination of its constitution was held not inventive.); Ex parte Sparhawk, 64 USPQ 339 , in which the claimed composition held unpatentable was a musk-like extract of muskrat gland; and Ex parte Snell, supra, in which the claims to vitamin $B_6$ or pyridoxamine, were held to be directed to a naturally occurring material.

In Ex parte Roberts et al., Patent File, 2,937,206, we came to a different conclusion because it appeared that appellants therein had not merely obtained a product having the same utility as the substance from which it was isolated or a product which differed only in purity, but that the compound claimed had a new utility not evident from the art. This holding was therefore in conformity with the principle recognized in the Merck and Sterling cases.

Appellants also urge that the "critical fact is that a-lipoic acid does not exist as such in nature but only a substance from which it can be produced by methods discovered by applicants." Whether the acid exists as such in liver or is in combined form and is freed from the combination by hydrolysis does not appear controlling or material in this type of case in view of the holdings in In re Ridgway, supra, General Electric Co. v. DeForest Company, supra, In re Macallum et al., supra, Ex parte Cavallito, supra, and Ex parte Stoll et al., supra. That alpha-lipoic acid is present in liver is not only apparent from the patents cited by the examiner, but even the publications referred to by appellants establish this fact. While the latter publications are indicative that hot aqueous extract of liver does not give an appreciable quantity of the acid, as shown by the patents, it was common knowledge that the isolation thereof from liquor was possible though difficult. In fact, the publications show that the release of the acid from the parent material is more readily effected by an acid hydrolysis which is more drastic than the hot water hydrolysis. Moreover, appellants' disclosure of the manner in which the acid is recovered or separated from the parent liver material affords ample basis for considering the hydrolysis as a simple release from its combination in liver. We therefore see no distinction in this respect and since there is no disclosure that the extracted material possesses a utility not possessed by the parent material, the Merck and Sterling cases are not controlling herein. Accordingly, we find no reversible error in the examiner's refusal of claims 12 and 13, and we will sustain the rejection.

The affidavit filed March 23, 1961, under Rule 195 was considered by the examiner on remand as relating to a utility not disclosed herein, In re Stewart, 42 CCPA 937, 1955 C. D. 249, 698 O. G. 516, 222 F.2d 747, 106 USPQ 115, and he accordingly was not convinced or persuaded of any inventiveness herein. Since we fully agree with the examiner's views, further consideration or discussion of this affidavit is unnecessary.

[3] The examiner has also rejected claims 12, 15 and 16 as being so "unduly broad in esters" as to fail to define the invention, the examiner stating that the term "lower alkyl esters" is inclusive of branched-chain alkyl compounds for which there is no support in the specification. The examiner considers that an enormous number of compounds are thus covered by the claims, which compounds he states would not necessarily have the same utility. However, we cannot agree with the examiner in this respect, because homologues and isomers are presumed to have the same utility differing normally as a matter of degree. Since appellants disclose at least three lower alkyl groups and have disclosed that the *lower* alkyl esters are preferred, we believe the claims are adequately supported. We, therefore, will not sustain the rejection.

[4] The examiner has also rejected claim 12 as "unduly broad in salts," as including toxic as well as non-toxic materials and as being unsupported by the specification. Claim 17 has been rejected as unpatentable over the acid, the examiner stating that no invention is involved in preparing simple salts of



any acid, as this is a well-known chemical principle. We are not convinced of any error in these rejections. In fact appellants in their brief concede that the salts are prepared by the conventional procedure of neutralization. Accordingly, the salts would be readily apparent and thus obvious to one skilled in the art, particularly as there is nothing patentable in the broad idea of forming the salts. (In re Williams, 38 CCPA 1026, 1951 C. D. 345, 649 O. G. 912, 188 F.2d 509, 89 USPQ 396.) Furthermore, appellants have specifically disclosed only the simple salts as giving the desired result and this affords insufficient basis for assuming that all metals of the periodic system will be suitable for the same intended purpose. We, therefore, will sustain these rejections.

The appeal is dismissed as to claims 14 and 18.

The decision of the examiner is affirmed as to claims 12, 13 and 17 but reversed as to claims 15 and 16.

**- End of Case -**

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